Remarks

Applicant has carefully considered this Application in connection with the Examiner's Action, and respectfully requests reconsideration of this Application in view of the foregoing amendment, and the following remarks.

Claims 6 – 10 and 12 have been withdrawn from consideration following the restriction/election requirement response filed on December 3, 2007. Applicant affirms the election of Group I directed to a compound of Formula I as recited in Claim 5. Applicant affirms the election of the disease state of behavioral agitation. Such election is made with the provisio that non-elected subject matter may be pursued at a later time in a continuation application, for example a divisional or continuation-in-part application.

Per the request of the Examiner at page 2 the Office Action, Applicant affirms the election of species of Group I, wherein R_1 is hydrogen and R_2 is hydroxy, in Claim 5.

Claim 5 is currently amended to reflect that the term "oxy" should be "oxo". This amendment is made to present the correct terminology for the functional group of Formula I. According to IUPAC Compendium of Chemical Terminology, "oxo" compounds are those containing an oxygen atom, =O, doubly bonded to carbon or another element. The term thus embraces aldehydes, carboxylic acids, ketones, sulfonic acids, amides and esters. Oxo used as an adjective (and thus separated by a space) modifying another class of compound, as in oxo carboxylic acids, indicates the presence of an oxo substituent at any position. See: PAC, 1995, 67, 1307 (Glossary of class names of organic compounds and reactivity intermediates based on structure (IUPAC Recommendations 1995)) on page 1355, which can be seen at the following site on the web-based version of the IUPAC Goldbook: http://goldbook.iupac.org/O04377.html. A copy of the website printout is attached hereto for the Examiner's convenience.

Thus, "oxo" is the correct adjective for the functional group presented at Claim 5 and not, as previously presented, "oxy". Support for the amendment can be found at the specification at Paragraph 0004 of Pub. No. 2007/0066593, which describes oxcarbazepine.

Additional claims 13 – 18 are newly added by this amendment to further define and particularly point out what Applicant regards as the invention. Support for newly

added claims can be found in the specification, specifically at Paragraphs 0090, 0019 – 0021 of Pub. No. 2007/0066593 and pages 4, lines 4-5 and 5, lines 17-18 of the application as originally filed, as well as in Claims 9 and 10 as filed. No new matter has been added.

Accordingly, Claims 5, and 13 – 18 are presently pending in the Application, with Claim 5 being the independent claim.

I. Rejection of Claim 5 under 35 U.S.C. § 112, first paragraph

The Examiner has rejected Claim 5 under 35 U.S.C. § 112, first paragraph because, according to the Examiner, the specification does not provide enablement for a method of treating Alzheimer's disease and does not allow the skilled artisan to practice the invention without undue experimentation. In light of amendment to Claim 5, Applicant respectfully traverses the rejection.

Claim 5, as amended, recites a method for the treatment of behavioral agitation, not a treatment for Alzheimer's disease itself. Moreover, Applicant guides the Examiner to Applicant's specification, specifically Para 0009 of Publication No 2007/0066593, where Applicant details an 8-week study on the treatment of behavioral agitation in elderly patients suffering from dementia, specifically Alzheimer's disease. Included in the working example are specific dosing regimens and outcome measurements. Behavioral agitation was measured using the 38-item Cohen-Mansfield Agitation Inventory (CMAI) that evaluates the prevalence of pathological and disruptive agitated behavior. Significant reductions in CMAI scores were seen using compounds of Formula I as recited by Applicant at Claim 5. Reductions in CMAI scores are further detailed in Para 0010 of Applicant's specification.

Thus, Applicant respectfully asserts that, contrary to Examiner's statement, no undue experimentation would be required to practice the invention commensurate in scope with Claim 5 because a working example is provided. As such, Applicant respectfully requests that the rejection of Claim 5 under 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn.

II. Rejection of Claim 5 under 35 U.S.C. § 112, second paragraph

The Examiner has rejected Claim 5 under 35 U.S.C. § 112, second paragraph as being indefinite. Specifically, the Examiner states that a broad range or limitation

together with a narrow range or limitation that falls within the broad range – in the same claim – is considered indefinite. Applicant respectfully asserts that in light of the amendment to Claim 5 to recite a method of treatment of behavioral agitation, the rejection of Claim 5 is moot.

The recitation of a method of treatment of behavioral agitation clearly sets forth the metes and bounds of the patent protection desired with clarity pursuant to MPEP § 2173.02. No limitation within a broad range exists within the scope of amended Claim 5. As such, Applicant respectfully requests that the rejection under 35 U.S.C. § 112, second paragraph be reconsidered and withdrawn.

III. Rejection of Claim 5 under 35 U.S.C. § 102(b)

The Examiner has rejected Claim 5 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 3,637,661, issued to Schindler (herein referred to as Schindler). The Examiner also cites definitions of "epilepsy" and "agitation" from Merriam-Webster's on-line dictionary in support of the rejection.

The Examiner cites Schindler for teaching a method of treating epilepsy. The Examiner goes on to cite Merriam-Webster Dictionary's definition of epilepsy as "a disorder manifested by sudden brief episodes of altered or diminished consciousness, involving involuntary movements or convulsions". Further cited from Merriam-Webster is the definition of agitation as "a movement with an irregular, rapid, or violent action". Based on these definitions, the Examiner concludes that the convulsions of epilepsy can be a form of agitation.

Applicant respectfully disagrees with this conclusion, which Applicant believes is rooted partially in the Examiner's erroneous statement on Page 8 of the Office Action that "any disease where a characteristic of the disease includes agitation would anticipate Applicant's invention". Applicant's Claim 5 does not include any disease where agitation is a characteristic, but rather teaches the pathological condition of behavioral agitation, commonly experienced by patients suffering dementia and Alzheimer's disease.

Moreover, it is well settled that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." MPEP §2131 (quoting *Verdegaal Bros. v. Union Oil Co. of*

Calif., 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). "The identical invention must be shown in as complete detail as is contained in the . . . claim." *Id.* (quoting *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)) Therefore, Schindler must describe each and every element of the claims in order to anticipate under Section 102(b).

Applicant respectfully submits that Schindler does not teach each and every element of Applicant's claims. More specifically, Schindler, at Col. 1, lines 43-53, expressly teaches the compound 10-hydroxy-10,11-dihydro-5H-dibenz(b, f)azepine-5-carboxamide as being suitable for the treatment of epilepsy, neuralgia and cerebral spasticity in mammals. Nowhere does Schindler discuss or even mention behavioral agitation, dementia or Alzheimer's disease. The Examiner has attempted to equate the involuntary physical movement associated with an epileptic episode as agitation, yet even if it were it is not the equivalent of behavioral agitation. Behavioral agitation is a specific form of agitation that is commonly associated with dementia and can be evaluated clinically such as described by Applicant at Paragraph 0009 of Applicant's specification.

Applicant's method of treating behavioral agitation is clearly not taught by Schindler, which is solely dedicated to treating epilepsy. Therefore, Schindler cannot anticipate Claim 5 under 35 U.S.C. §102 (b), and Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claim 5 under 35 U.S.C. § 102(b).

IV. Double Patenting.

Claim 5 stands rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over Claim 1 of co-pending U.S. Patent Application No. 10/550,382, which is a U.S. patent application commonly owned by the Assignee of Applicant's invention, Novartis AG. (See Office Action, page 10.)

Applicants defer responding to this rejection until patentable subject has been determined at which time Applicants will consider whether a terminal disclaimer is needed.

V. Conclusion

In view of the foregoing, Claim 5 and newly added claims 13 – 18 are in condition for allowance, and Applicant earnestly solicits a Notice of Allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this Application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration to this Amendment and Reply is respectfully requested.

Respectfully submitted,
Montgomery, McCracken, Walker & Rhoads, LLP

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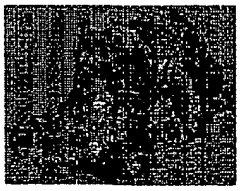

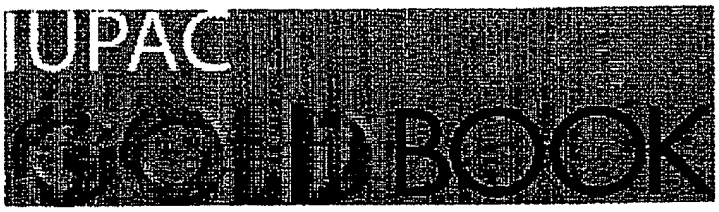

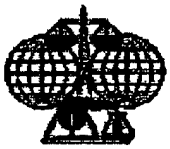

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PREVIOUS
oxo carboxylic acids

oxo compounds

Compounds containing an oxygen atom, **=O**, doubly bonded to carbon or a term thus embraces **aldehydes, carboxylic acids, ketones, sulfonic aci** Oxo used as an adjective (and thus separated by a space) modifying anotl as in **oxo carboxylic acids**, indicates the presence of an oxo substituent a indicate a double-bonded oxygen that is part of a ketonic structure, the ter used as a prefix, but such use has been abandoned by IUPAC for naming traditional use of **keto** is for indicating **oxidation** of **CHOH** to **C=O** in a par contains **OH** groups, such as **carbohydrates**, e.g. 3-ketoglucose.

See: **ketoaldonic acids, ketoaldoses**

Source:
PAC, 1995, *67*, 1307 *(Glossary of class names of organic compounds and based on structure (IUPAC Recommendations 1995))* on page 1355

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	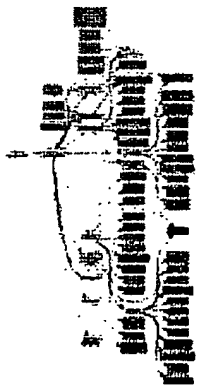	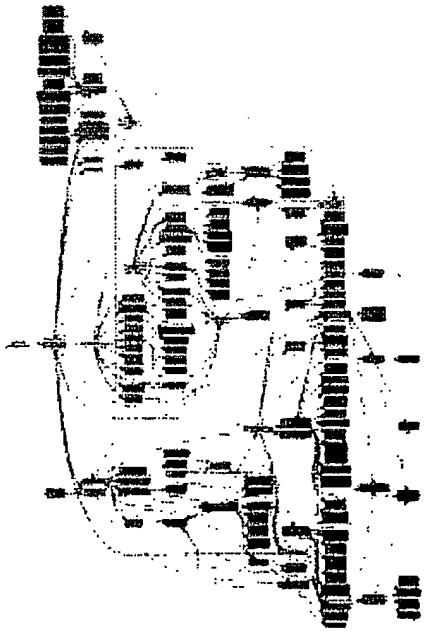

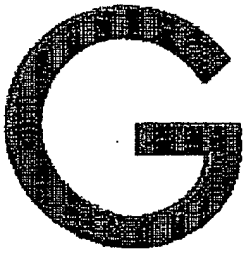

Cite as: IUPAC Compendium of Chemical Terminology, Electronic version, http://goldbook.iu

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by: Miloslav Nic, Jiri Jirat, Bedrich Kosata, ICT Prague, Czech Republic

Vers

oxo compounds

Compounds containing an oxygen atom, **=O**, doubly bonded to carbon or another element. The term thus embraces **aldehydes, carboxylic acids, ketones, sulfonic acids, amides** and **esters**. Oxo used as an adjective (and thus separated by a space) modifying another class of compound, as in **oxo carboxylic acids**, indicates the presence of an oxo substituent at any position. To indicate a double-bonded oxygen that is part of a ketonic structure, the term **keto** is sometimes used as a prefix, but such use has been abandoned by IUPAC for naming specific compounds. A traditional use of **keto** is for indicating **oxidation** of **CHOH** to **C=O** in a parent compound that contains **OH** groups, such as **carbohydrates**, e.g. 3-ketoglucose.

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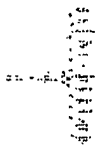		

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